DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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January 27, 2015

Miromatrix Medical Incorporated
% Mr. Stephen Rhodes
Biologics Consulting Group Incorporated
400 North Washington Street, Suite 100
Alexandria, Virginia 22314

Re: K143426
Trade/Device Name: Wound Matrix TF
Regulatory Class: Unclassified
Product Code: KGN
Dated: December 30, 2014
Received: December 31, 2014

Dear Mr. Rhodes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143426

Device Name
Wound Matrix TF

Indications for Use *(Describe)*

Wound Matrix TF is intended for the management of wounds including:

- Partial and full thickness wounds;
- Pressure ulcers;
- Venous ulcers;
- Diabetic ulcers;
- Chronic vascular ulcers;
- Tunneled, undermined wounds;
- Surgical wounds (donor sites/grafts, post-Mohs' surgery, post-laser surgery, podiatric, wound dehiscence);
- Trauma wounds (abrasions, lacerations, second-degree burns, and skin tears);
- Draining wounds.

The device is supplied sterile and is intended for one-time use.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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5. 510(K) SUMMARY

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for Wound Matrix TF is provided below.

Device Common Name: Animal-derived, extracellular matrix wound care product

Device Proprietary Name: Wound Matrix TF

Submitter:
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Date Prepared: November 29, 2014

Classification Regulation: Unclassified

Panel: General & Plastic Surgery

Product Code: KGN

Predicate Device: K140510, Miromatrix Wound Matrix

Reference Device: K061711, Cook Biotech Oasis® Wound Matrix

Indication for Use:

Wound Matrix TF is intended for the management of wounds including:

- Partial and full thickness wounds;
- Pressure ulcers;

- Venous ulcers;
- Diabetic ulcers;
- Chronic vascular ulcers;
- Tunneled, undermined wounds;
- Surgical wounds (donor sites/grafts, post-Mohs' surgery, post-laser surgery, podiatric, wound dehiscence);
- Trauma wounds (abrasions, lacerations, second-degree burns, and skin tears);
- Draining wounds.

The device is supplied sterile and is intended for one-time use.

Device Description:

Wound Matrix TF is an animal-sourced, acellular wound dressing that is derived from porcine liver tissue. The liver tissue undergoes perfusion decellularization and the resulting wound dressing is comprised primarily of collagen type I. The device is intended for use in the management of wounds. Wound Matrix TF is terminally sterilized in its packaging and is hydrated, moist and flexible when its packaging is opened. The dressing is available in sizes ranging from 1 cm x 2 cm to 10 cm x 25 cm, and may be trimmed or cut as required.

Comparison of the Technical Characteristics with the Predicate Device:

The only modification made the device since its previous clearance in K140510 is the addition of fenestrations and a reduction in the minimum thickness specification from 0.3 mm to 0.1 mm.

Performance Data:

Verification and validation testing was conducted to confirm that bioburden, endotoxin and device dimensions were within the specified values in accordance with the risk assessment.

Substantial Equivalence:

The addition of fenestrations and reduced minimum thickness is achieved by the physical cutting of the matrix under quality controlled processes. Wound Matrix TF is substantially equivalent to the predicate device with respect to the indications for use, materials, manufacturing processes, packaging, sterilization, and shelf life.

Conclusion/Summary of SE argument

The substantial equivalence of Wound Matrix TF was established based on a declaration of conformity to design control requirements and on an assessment of the effects of the changes to the predicate device based on a risk assessment. Wound Matrix TF is substantially equivalent to the Miromatrix Wound Matrix predicate device with respect to material composition, device characteristics and intended use.